

REMARKS/ARGUMENTS

Favorable reconsideration of this application as presently amended and in light of the following discussion is respectfully requested.

Applicants thank the Examiner for the discussion with the Applicants' representatives on March 22, 2005. The content of that discussion is reflected and further expanded in the remarks herein.

Claims 1-14, 36-39, 42, and 43 are now pending in this application. Claims 15-35, 40, and 41, are withdrawn from consideration due to a restriction requirement, and are herein canceled without prejudice. Claim 37 has been allowed for which Applicants thank the Examiner. Claims 1, 4, 36, and 42 are currently amended. Claim 43 is added. Support for the amendment of the claims is found at least in original claim 4. Support for claim 43 is found at least in original claim 1 and in the specification at paragraphs 0088-0106. No new matter has been added.

In the outstanding Office Action, claim 42 was rejected under 35 U.S.C. § 112, paragraph two, as indefinite. Claims 1, 2, 6-9, 12, 13, 36, and 42 were rejected under 35 U.S.C. § 102(b) as anticipated by Sohn, WO 97/47246. Claims 3 and 4 were rejected under 35 U.S.C. § 103(a) as obvious over Sohn in view of Berger, Pat. App. Pub. US 2002/0091373. Claim 11 was rejected under 35 U.S.C. § 103(a) as obvious over Sohn in view of Cook, 1996. Claim 14 was rejected under 35 U.S.C. § 103(a) as obvious over Sohn in view of Allosling Fascia, 1999. Claims 38 and 39 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claim 62 of co-pending U.S. Application No. 10/005,837. Claims 5 and 10 were objected to as depending from a rejected base claim.

Claim 1 was rejected under 35 U.S.C. § 102(b) as anticipated by Sohn, WO 97/47246.

Claim 1 is herein amended, and it is believed such amendment overcomes the rejection over Sohn.

Claim 1 of the present invention, as amended, is directed to a surgical kit for treating incontinence. The kit comprises an implantable material suitable for a sling procedure, at least one of a first type of needle suitable for a sling procedure, at least one of a second type of needle suitable for a sling procedure, wherein the first type of needle is different than the second type of needle, and an adapter for associating said implantable material suitable for a sling procedure with at least one of said needles. Claims 2-14 depend directly or indirectly from claim 1.

Sohn discloses a suture insertion device for the treatment of urinary stress incontinence. Sohn discloses an implantable sling material and two different types of needles. Sohn does not disclose or suggest an adapter for associating the implantable sling material with at least one of the surgical needles. Despite the assertion in the Office Action that the “sutures of Sohn prove an adapter for associating the sling and the surgical needle” (Office Action, page 5, lines 1 and 2), it is clear that there is no disclosure of such an association between the needle and sling of Sohn. The adapter of the present invention facilitates the attachment of the sling material to the surgical needle. Sohn discloses that the needles are used to insert suture through bony structure, to which the implantable sling material may be suspended. The sutures of the Sohn invention serve to support an implantable sling after the needle has been disassociated, not to associate the needle with the sling. Accordingly, Sohn does not disclose or suggest the adapter of amended claim 1. Hence, the claim is patentably distinct.

Claims 2, 6-9, 12, and 13 were likewise rejected under 35 U.S.C. § 102(b) as anticipated by Sohn. These claims all depend directly or indirectly from claim 1, which as

discussed, is now believed to be allowable. Accordingly, Applicants' respectfully request the withdrawal of these rejections and the allowance of claims 2, 6-9, 12, and 13.

Claims 3 and 4 were rejected under 35 U.S.C. § 103(a) as obvious over Sohn in view of Berger, Pat. App. Pub. US 2002/0091373. Claim 3 of the present invention is drawn to a kit as claimed in amended claim 1, further including a synthetic insertion sheath associated with the implantable material to form a sling assembly. Claim 4 depends from claim 3, and claims the further modification of the adapter of claim 1 as amended. The Office Action concedes that Sohn fails to teach the synthetic insertion sheath. However, the Office Action asserts that it would have been obvious to include a sheath as taught by Berger. Applicants respectfully traverse that assertion.

When obviousness is based on the teachings of multiple prior art references, some suggestion, teaching, or motivation must be established that would have lead a person of skill in the art to combine the relevant prior art teachings. *Tec Air, Inc. v. Denso Mfg. Mich. Inc.*, 192 F.3d 1353, 1359-60 (Fed. Cir. 1999). One skilled in the art must have had some motivation to combine the teachings of the references in the particular manner claimed. *In re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998). Such motivation must be found in the prior art to mitigate the "subtle but powerful attraction of hind-sight based obviousness analysis". *Teleflex, Inc. v. KSR Int'l Co.*, 119 Fed. Appx. 282,285 (Fed. Cir. 2005). The Office has failed to provide evidence of such motivation from the cited references in this instance, raising the specter of hind-sight based analysis. Without such evidence, one skilled in the art would not have been motivated to combine the teachings of Sohn, which is directed to a device for insertion of suture into bone, with the very different device of Berger, which is directed to a sling apparatus in which the device does not utilize attachment to the bone. Lacking such motivation, Applicants respectfully submit that the obviousness rejection is improper, and that the rejection of claims 3 and 4 should be withdrawn and the claims

allowed. Further, the adapter claimed in amended claim 1, and further adapted in claim 4, is not believed to be disclosed in either Sohn or Berger. Lacking this element, and lacking the requisite motivation to combine, the Office Action has failed to state a prima facie case of obviousness. Accordingly, Applicants request the withdrawal of the rejections of claims 3 and 4, and allowance of these claims.

Claim 11 was rejected under 35 U.S.C. § 103(a) as obvious over Sohn in view of the Cook Urogynecology reference. Claim 11 discloses a surgical kit according to claim 1 wherein the first type of needle includes at least two straight portions situated at a predetermined angle. As noted above, Sohn discloses an implantable sling material and two different types of needles, but does not disclose the adapter of claim 1, as amended. The Cook reference merely discloses a Stamey needle. Not disclosing the adapter of amended claim 1, Cook fails to remedy the deficiency of Sohn. Accordingly, the rejection of claim 11 should be withdrawn and the claim allowed.

Claim 14 was rejected under 35 U.S.C. § 103(a) as obvious over Sohn in view of Allosling Fascia, 1999. Claim 14 is directed to a surgical kit according to claim 1 wherein the first type of needle includes a bladder perforation detector. Sohn discloses an implantable sling material and two different types of needles, but does not disclose the adapter of claim 1, as amended. The Allosling reference fails to remedy the deficiency of Sohn, as Allosling also fails to disclose the adapter of claim 1, as amended. Accordingly, the rejection of claim 14 should be withdrawn and the claim allowed.

Claims 5 and 10 were objected to as depending from a rejected base claim. As it is believed that claims 4 and 9 are allowable, as discussed above, Applicants submit that these objections are moot, and request their withdrawal.

Claim 36 was rejected under 35 U.S.C. § 102(b) as anticipated by Sohn, WO 97/47246. Claim 36 of the present invention, as amended, discloses a surgical sling

procedure for treating incontinence. The disclosed procedure includes the steps of (1) providing a surgical kit with an implantable material suitable for a sling procedure, at least one of a first type of needle that is sized and shaped for inserting a sling, at least one of a second type of needle that is sized and shaped for inserting a sling, wherein the first type of needle is different than the second type of needle, and an adapter for associating said implantable material suitable for a sling procedure with at least one of said needles, (2) selecting the first or the second type of needle, and (3) implanting the implantable material using the selected needle.

Sohn discloses an implantable sling material and two different types of needles, but does not disclose an adapter for associating the implantable material suitable with at least one of the needles. Sohn does not disclose “implanting the implantable material using the selected needle”, as it discloses the use of the needles to insert suture through bony structure, to which the sling material may be attached following detachment of the needles. Not disclosing all the limitations of the claim, Sohn cannot anticipate claim 36. Accordingly, Applicants submit that this rejection should be withdrawn and the claim allowed.

Claims 38 and 39 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claim 62 of co-pending U.S. Application No. 10/005,837. As neither application has matured into a patent, Applicants request that this rejection be held in abeyance until allowable subject matter is found.

Claim 42 was rejected under 35 U.S.C. § 102(b) as anticipated by Sohn, WO 97/47246, and under 35 U.S.C. § 112, paragraph two, as indefinite. In response to the indefiniteness rejection, claim 42 has been amended to remedy the alleged indefiniteness. Support for the amendment of claim 42 is found at page 34 and 35, paragraphs 00173-00175 of the specification. Accordingly, Applicants request withdrawal of this rejection.

With regard to the rejection of claim 42 as anticipated by Sohn, Applicants respectfully submit that, as now amended, the Office Action fails to state a prima facie case of anticipation. Claim 42 now claims a surgical kit for treating incontinence. The surgical kit comprises (1) an implantable material suitable for a sling procedure, (2) a needle that is sized and shaped for inserting a sling, the needle having surfaces for engaging a handle, (3) an adapter for associating said implantable material suitable for a sling procedure with said needle, (4) at least one of a first type of handle having surfaces for attaching the handle to the needle, and (5) at least one of a second type of handle having surfaces for attaching the handle to the needle. The first type of handle is different than the second type of handle.

Sohn discloses an implantable sling material and two different types of needles, but does not disclose an adapter for associating the implantable sling with a needle. Not disclosing all the limitations of the claim, Sohn cannot anticipate claim 42. Accordingly, Applicants submit that this rejection should be withdrawn and the claim allowed.

Submitted herein is a Supplemental Information Disclosure Statement. The Office noted in its Office Action that certain references in the Form 1449 submitted on June 1, 2004 were not considered because certain information was not provided. Applicants herein provide more complete information for most of the previously not-considered references to correct earlier inadvertent omissions. Due consideration of such references is respectfully requested.

In light of the above discussion and the present amendment, the present application is believed to be in condition for allowance. An early and favorable action to that effect is respectfully requested.

Application No. 10/675,816  
Reply to Office Action of December 3, 2004

Respectfully submitted,

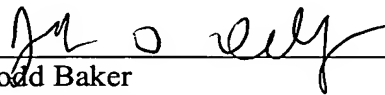
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